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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/672,069	09/25/2003	Tariq M. Rana	UMY-062	4721

959 7590 07/12/2006

LAHIVE & COCKFIELD  
28 STATE STREET  
BOSTON, MA 02109

EXAMINER

CHONG, KIMBERLY

ART UNIT PAPER NUMBER

1635

DATE MAILED: 07/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/672,069	Applicant(s) RANA, TARIQ M.	
	Examiner Kimberly Chong	Art Unit 1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 24 April 2006.
- 2a) ☐ This action is FINAL.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☐ Claim(s) \_\_\_\_\_ is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1,3,4,19,21,22,27 and 84-108 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Election/Restrictions***

This is a supplemental restriction requirement based on applicant's amendment and addition of new claims filed after the non-final action 04/24/2006.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1, 3-4, 33, 39, 84 and 86-90 drawn to a siRNA comprising an antisense and sense strand wherein the antisense strand is modified by the substitution of each uridine with 2'-fluoro uridine and each cytidine with 2'-fluoro cytidine, classifiable in class 536, subclass 24.5.
- II. Claims 19, 34, 39, 91 and 95-97, drawn to a siRNA comprising an antisense and sense strand wherein the antisense strand is modified by the substitution of each uridine with 5-bromo uridine, classifiable in class 536, subclass 24.5.
- III. Claims 21, 35, 39 and 98-100, drawn to a siRNA comprising an antisense and sense strand wherein the antisense strand is modified by the substitution of each phosphodiester linkages with a phosphorothioate linkage, classifiable in class 536, subclass 24.5.
- IV. Claims 22, 39 and 98-100, drawn to a siRNA comprising an antisense and sense strand wherein the antisense strand and the sense strand is modified by the substitution of each phosphodiester linkages with a phosphorothioate linkage, classifiable in class 536, subclass 24.5.

- V. Claims 27, 36, 39 drawn to a siRNA comprising an antisense and sense strand wherein the antisense strand is complementary to the sense strand throughout the siRNA but for mismatched base pairs at the two 3' nucleotides referencing the antisense strand, classifiable in class 536, subclass 24.5.
- VI. Claims 85-90 and 39, drawn to a siRNA comprising an antisense and sense strand wherein the antisense strand and the sense strand are modified by the substitution of each uridine with 2'-fluoro uridine and each cytidine with 2'-fluoro cytidine, classifiable in class 536, subclass 24.5.
- VII. Claims 92-98 and 39, drawn to a siRNA comprising an antisense and sense strand wherein the antisense strand is modified by the substitution of each uridine with 5-iodo uridine, classifiable in class 536, subclass 24.5.
- VIII. Claims 101-102, 36 and 39 and 106-108, drawn to a siRNA comprising an antisense and sense strand wherein the antisense strand is modified by the substitution of each purine with 2,6 diaminopurine classifiable in class 536, subclass 24.5.
- IX. Claims 103-108 and 39 drawn to a siRNA comprising an antisense and sense strand wherein the siRNA is modified within the 5' half of the siRNA referencing the antisense strand and unmodified within the 3' half of the siRNA referencing the antisense strand, classifiable in class 536, subclass 24.5.

Art Unit: 1635

The inventions are distinct, each from the other because of the following reasons:

Inventions I-IX are directed to related siRNA comprising a sense strand and an antisense strand wherein the antisense strand is complementary to the sense strand and has a sequence sufficiently complementary to a target mRNA. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j).

In the instant case, the siRNA are mutually exclusive because each siRNA has a materially different design and are not obvious variants. For example, group I is drawn to siRNA wherein the antisense strand is modified by the substitution of each uridine and cytidine with 2'-fluoro uridine and 2'-fluoro cytidine which has a materially different design than the siRNA of group II wherein the antisense strand is modified by the substitution of each uridine with 5-bromo uridine and materially different than the siRNA of groups III and IV which are drawn to an siRNA wherein the antisense strand or both the antisense and sense strand is modified by the substitution of each phosphodiester linkages with a phosphorothioate linkage. Further, the siRNA of groups I-IV are materially different than the siRNA of group V wherein the antisense strand is complementary to the sense strand throughout the siRNA but for mismatched base pairs at the two 3' nucleotides referencing the antisense strand, materially different than the siRNA of group VI wherein both the antisense strand and the sense strand are modified by the substitution of each uridine with 2'-fluoro uridine and each cytidine with

Art Unit: 1635

2'-fluoro cytidine and materially different than the siRNA of group VII wherein the antisense strand is modified by the substitution of each uridine with 5-iodo uridine. Additionally, the siRNA of groups I-VII have a materially different design than the siRNA of group VIII wherein the antisense strand is modified by the substitution of each purine with 2,6 diaminopurine and group IX wherein the siRNA is modified within the 5' half of the siRNA referencing the antisense strand and unmodified within the 3' half of the siRNA referencing the antisense strand. Moreover, the siRNA of groups I-IX are not disclosed as capable of use together. Furthermore restriction is proper because the subject matter is divergent and non-coextensive and a search for one would not necessarily reveal art against the other. It is therefore a burden to search these inventions in a single application.

Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim

Art Unit: 1635

remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

### ***Conclusion***

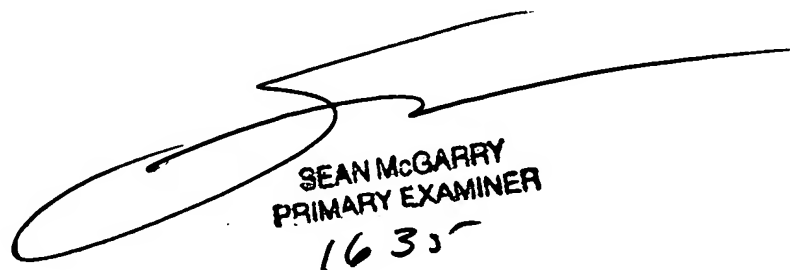
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kimberly Chong whose telephone number is 571-272-3111. The examiner can normally be reached Monday thru Friday between 7-4 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached at 571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Kimberly Chong  
Examiner  
Art Unit 1635



SEAN MCGARRY  
PRIMARY EXAMINER  
1635